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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,591	12/21/2001	Eugene Medlock	01017/37128C	6379

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	14

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,591	MEDLOCK ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendment in paper No. 4, filed on 24 June 2002 is acknowledged and entered. Following the amendment, claims 4, 12, 16, 18-26, 28, 31, 50, 51, 54, 57, 59, 60, 62-67, 70, 73 and 74 are amended.

Currently, claims 1-78 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10, and 11, drawn to an isolated nucleic acid, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 9, 13-26, 60, 61, and 68, drawn to an isolated polypeptide, and a fusion protein thereof, classified in class 530, subclass 350.

III. Claim 12, drawn to a process for determining the polypeptide inhibiting activity of a compound, classified in class 435, subclass 7.

IV. Claims 27-30, 32-47, 49, and 50, drawn to an antibody or fragment thereof, and a hybridoma thereof, classified in class 530, subclass 387.9.

V. Claim 31, drawn to a method of detecting or quantifying the polypeptide with the antibody, classified in class 435, subclass 7.

VI. Claims 48, and 69-73, drawn to a method of treating, preventing, or ameliorating a IL-17 like polypeptide related disease, condition, or disorder with the antibody, classified in class 424, subclass 139.1.

VII. Claims 51-56, 62, and 78, drawn to a composition of the polypeptide, and a method of treatment using the polypeptide, classified in class 514, subclass 2.

VIII. Claims 57-59, drawn to a composition of the nucleic acid, classified in class 435, subclass 320.1.

IX. Claim 63, drawn to a method of diagnosis by determining the presence or amount of the polypeptide, classification depending upon the method steps.

X. Claim 64, drawn to a device, classified in class 424, subclass 93.2.

XI. Claim 65, drawn to a method of identifying a compound binding to the polypeptide, classified in class 435, subclass 7.

XII. Claim 66, drawn to a method of modulating levels of the polypeptide in an animal by administering the nucleic acid, classified in class 514, subclass 44.

XIII. Claim 67, drawn to a transgenic non-human mammal comprising the nucleic acid, classified in class 800, subclass 14.

XIV. Claims 74-76, drawn to a method of antagonizing the activity of an IL-17 like polypeptide, or treating a condition with an IL-17 like polypeptide antangonist, classification depending upon species.

XV. Claim 77, drawn to a method of treating a condition with an IL-17 like polypeptide angonist, classification depending upon species.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and the protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

Invention I is related to Inventions III and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the polypeptide of Invention II.

The nucleic acid of Invention I is distinct from and unrelated to the antibody of Invention IV, the device of Invention X, and the transgenic animal of Invention XIII, because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the products of Inventions IV, X, and XIII as they may be neither made by nor used in the method.

Invention I is distinct from and unrelated to Inventions V-VII, IX, XI, XIV, and XV, wherein the nucleic acid of Invention I is neither made by nor used in the methods of Inventions V-VII, IX, XI, XIV, and XV, and wherein each does not require the other.

The nucleic acid of Invention I is related to the composition of Invention VIII by virtue of being a part of the composition. However, they are distinct inventions because the composition comprised additional active ingredient, the viral vector, which is a physically and functionally distinct chemical entity, thus requires non-coextensive searches are required. Additionally, the nucleic acids may be used for processes other than the production of the transgenic animal, such as nucleic acid hybridization assay. Further, Invention I does not require Invention VIII.

The nucleic acid of Invention I is related to the transgenic mammal of Invention XIII by virtue of being the transgene in the transgenic mammal. However, they are distinct inventions because they are physically and functionally distinct chemical entities, and the nucleic acids may be used for processes other than the production of the transgenic, non-human mammal, such as nucleic acid hybridization assay. Further, Invention I does not require Invention XIII.

Invention II is distinct from and unrelated to Inventions III, V, VI, IX, XII, XIV, and XV, wherein the polypeptide of Invention II is neither made by nor used in the methods of Inventions III, V, VI, IX, XII, XIV, and XV, and wherein each does not require the other.

The polypeptide of Invention II is related to the antibody of Invention IV by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and

because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention II is related to Inventions VII and XI, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating the antibody of Invention IV.

The polypeptide of Invention II is distinct from and unrelated to the products of Inventions VIII, and XIII because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The polypeptide of Invention II is related to the device of Invention X by virtue of being the secreted protein of the device. However, they are distinct inventions because the device comprised other active ingredient, the membrane, which is a physically and functionally distinct chemical entity, thus requires non-coextensive searches are required. Additionally, the polypeptide may be used for processes other than the production of the device, such as generating antibodies. Further, Invention II does not require Invention X.

Invention IV is related to Inventions V, VI, and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for purifying the polypeptide of Invention II.

Invention IV is distinct from and unrelated to Inventions III, VII, IX, XI, and XIV, wherein the antibody of Invention IV is neither made by nor used in the methods of Inventions III, VI, X, XI, XIV, and XV, and wherein each does not require the other.

The antibody of Invention IV is distinct from and unrelated to the products of Inventions VIII, X, and XIII because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

Inventions V-XIV are drawn to independent methods (Inventions V-VII, IX, XI, XII, XIV, and XV) and products (Inventions VIII, X, and XIII), wherein each of the methods is distinct and unrelated to the other methods, each not requiring the other, each of the products is distinct and unrelated to the other products, being drawn to distinct entities which require non-coextensive searches, and the products are not required for the methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, if applicants elect any one of the groups set forth above, further **restriction** is required under 35 U.S.C. 121:

A. One specific nucleotide sequence and its corresponding amino acid sequence with SEQ ID NO:, i.e. SEQ ID NO:1 and 2; 3 and 4; or 9 and 10.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - XV, and one from Group A, even though the requirement is traversed. Applicant is advised that

neither I - XV nor A are species election requirements; rather, each of I – XV, and A is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Species Election

If applicants elect group XIV, a further election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: there are four different antagonists of IL-17 receptor like polypeptide activity listed in claim 74, i.e., said polypeptide, IL-17 like selective binding agents, small molecules, antisense oligonucleotides, and peptides. Each listed type of agents has a distinct structure and function from the others, is separately classified, and each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
3/11/03